Availability

The reports of the health effects studies listed below are now available through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22151, telephone 1–800–553–6847. There is a charge for these items as determined by NTIS.

Health effects study	NTIS document No.
Pancreatic Cancer Mortality and Residential Proximity to Railroad Refueling Facilities in Montana. ATSDR/HS–95/45	PB95–191359
Biologic Indicators of Exposure to Heavy Metals in Fish Consumers, American Samoa. ATSDR/HS–95/46	PB95–182994
Multisite Lead and Cadmium Exposure Study with Biological Markers Incorporated. ATSDR/HS–95/47	PB95–199188
Madison County Lead Exposure Study. ATSDR/HS–95/48	PB95–209631
Missouri Respiratory Study: Forest City and Glover, Missouri. ATSDR/HS–95/49	PB95–212742
Symptom and Illness Prevalence with Biomarkers Health Study for Calvert City and Southern Livingston County, Kentucky. ATSDR/HS–95/50.	PB95–222808
Analytic Study to Evaluate Associations Between Hazardous Waste Sites and Birth Defects. ATSDR/HS–95/51	PB95–199196
National Exposure Registry, Benzene Subregistry, Baseline Technical Report. ATSDR/HS–95/52	PB95–255766
Development and Evaluation of a Statewide Surveillance System: Hazardous Waste Sites and Cancer Incidence in New York State. ATSDR/HS–95/53.	PB95–230553
Biologic Indicators of Exposure to Cadmium and Lead: Palmerton, Pa. Part II. ATSDR/HS–95/54	PB95–225207
End-Stage Renal Disease Study, New York. ATSDR/HS–95/55	PB95–25389
A Case-Control Study to Determine Risk Factors for Elevated Blood Lead Levels in Children: Silver Valley, Idaho. ATSDR/HS–95/56.	PB95–253837

In accordance with 42 CFR 90.11, copies of these final reports have been distributed to the Environmental Protection Agency, the appropriate State and local government agencies, and the affected local communities.

ATSDR previously announced the availability of 44 final reports of health effect studies and a software package for the analysis of disease clusters (55 FR 31445, August 12, 1990; 57 FR 29091, June 30, 1992; 58 FR 29413, May 20, 1993; 58 FR 63378, December 1, 1993; 59 FR 47879, September 19, 1994; and 60 FR 25236, May 11, 1995). Additional final reports will be announced semiannually in the Federal Register as they become available.

Dated: October 19, 1995.

Claire V. Broome,

Deputy Administrator, Agency for Toxic Substances and Disease Registry.

[FR Doc. 95–26445 Filed 10–24–95; 8:45 am]

BILLING CODE 4163–70–P

Food and Drug Administration

[Docket No. 94F–0395]

Ecological Chemical Products Co.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 4B4432), filed by Ecological Chemical Products Co., proposing that the food additive regulations be amended to provide for the safe use of 2-hydroxy-propanoic acid homopolymer and (2-hydroxy-propanoic acid/caprolactone) block copolymer as components of adhesives intended to contact food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 23, 1994 (59 FR 60364), FDA published a notice that it had filed a petition (FAP 4B4432) on behalf of Ecological Chemical Products Co., 305 Water St., Newport, DE 19804. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of 2-hydroxy-propanoic acid homopolymer and (2-hydroxy-propanoic acid/caprolactone) block copolymer as a component of adhesives intended to contact food. Ecological Chemical Products Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: October 10, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–26502 Filed 10–24–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0260]

Determination of Regulatory Review Period for Purposes of Patent Extension; ULTRAVIST®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ULTRAVIST® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs

(HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ULTRAVIST® (iopromide). ULTRAVIST® is indicated for intra-arterial digit subtraction and visceral angiography; cerebral, peripheral, and coronary arteriography; left ventriculography, aortography, peripheral venography, and contrast-enhanced, computed tomographic imaging of the head and body, and excretory urography. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ULTRAVIST® (U.S. Patent No. 4,364,921) from Schering Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 18, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ULTRAVIST® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ULTRAVIST® is 2,518 days. Of this time, 1,353 days occurred during the testing phase of the regulatory review period, while 1,165 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* June 19,1988. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 19, 1988.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* March 2, 1992. FDA has verified the applicant's claim that the new drug application (NDA) for ULTRAVIST® (NDA 20–220) was initially submitted on March 2, 1992.

3. *The date the application was approved:* May 10, 1995. FDA has verified the applicant's claim that NDA 20–220 was approved on May 10, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before December 26, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before April 23, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 5, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–26501 Filed 10–24–95; 8:45 am]

BILLING CODE 4160–01–F

Characterization of Biological/Biotechnology Pharmaceutical Products; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on Characterization of Biological/Biotechnology Pharmaceutical Products. The workshop will discuss the types of data that are necessary to characterize biological/biotechnology pharmaceutical products to assure their safety, identity, purity, potency, quality, and consistency. Discussions will address the current abilities and limitations of analytical technologies for characterization of biotechnology products.

DATES: The public workshop, to include plenary and technical breakout sessions, will be held on December 11, 12, and 13, 1995, from 8 a.m. to 5 p.m. Participants may pick up their information packages and badges for admission to the sessions beginning each morning at approximately 7:30 a.m.

ADDRESSES: The public workshop will be held at the Omni Shoreham Hotel, 2500 Calvert St. NW., Washington, DC 20008. There is no registration fee for this workshop, but advance registration is requested. Interested parties are encouraged to register early because space is limited.

FOR FURTHER INFORMATION CONTACT:

Regarding information on registration and other logistical matters contact: Dawn Apple, KRA Corp., 1010 Wayne Ave., suite 850, Silver Spring, MD 20910, 301–495–1591, or FAX 301–495–2919.

Regarding information on this document contact: Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–20), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0377, or FAX 301–827–0440.

SUPPLEMENTARY INFORMATION: FDA recognizes that there have been technology developments in process